Sunstar Americas Inc
Ms. Liz Bastian
Regulatory Affairs Manager
301 E. Central Road
Schaumburg, Illinois 60195

July 13, 2018

Re: K181134
Trade/Device Name: GUM HYDRAL Dry Mouth Oral Gel, GUM HYDRAL Dry Mouth Oral Rinse, GUM HYDRAL Dry Mouth Oral Spray
Regulatory Class: Unclassified
Product Code: LFD
Dated: April 27, 2018
Received: April 30, 2018

Dear Liz Bastian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181134

Device Name

G•U•M® HYDRAL™ Dry Mouth Oral Gel
G•U•M® HYDRAL™ Dry Mouth Oral Rinse
G•U•M® HYDRAL™ Dry Mouth Oral Spray

Indications for Use *(Describe)*

G•U•M® HYDRAL™ Dry Mouth Oral Gel helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

G•U•M® HYDRAL™ Dry Mouth Oral Rinse helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

G•U•M® HYDRAL™ Dry Mouth Oral Spray helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Manufacturer Name:	Sunstar Americas, Inc.
Address:	301 E. Central Rd. Schaumburg, IL
Contact Name:	Liz Bastian
Title:	Regulatory Affairs Manager
Phone Number:	847 794 4231
Date Prepared:	July 12, 2018

Device Proprietary Name:	G•U•M® HYDRAL™ Dry Mouth Oral Gel, G•U•M® HYDRAL™ Dry Mouth Oral Rinse G•U•M® HYDRAL™ Dry Mouth Oral Spray
Common or Usual Name:	Artificial Saliva
Classification Name:	Saliva, Artificial
Classification Code:	LFD
Regulation Number:	Unclassified
Device Classification	Unclassified
Review Panel	Dental Devices Panel

Predicate Device:

Biotene® Oral Balance® Dry Mouth Moisturizing Gel and Biotene Dry Mouth Oral Rinse and Biotene Dry Mouth Spray, K123731.

Description of the Device

G•U•M® HYDRAL™ Dry Mouth Oral Gel, G•U•M® HYDRAL™ Dry Mouth Oral Rinse and G•U•M® HYDRAL™ Dry Mouth Oral Spray are specifically formulated artificial saliva with a pH between 5.00 to 7.00. The proposed device is formulated with water, moisturizers /humectants including one plant-based moisture rich humectant, sweeteners and flavors that collectively have lubricating, moisturizing, soothing, and humectant, sweeteners and flavors that collectively have lubricating, moisturizing, soothing, and refreshing properties to help relieve and manage the symptoms of dry mouth.

The device is provided in a ready to use package for use at home. G•U•M® HYDRAL™ Dry Mouth Oral Gel is supplied in a 1.5-ounce Polyethylene Laminate tube. G•U•M® HYDRAL™ Dry Mouth Oral Rinse is supplied in a 16.9 fluid ounce bottle with a dose indicating cap, and G•U•M® HYDRAL™ Dry Mouth Oral Spray 1.69 fluid ounce bottle. Both rinse and spray are packaged in Polyethylene Terephthalate (PET) bottles with white polypropylene caps.

Intended Use/Indications for Use

G•U•M® HYDRAL™ Dry Mouth Oral Gel helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

G•U•M® HYDRAL™ Dry Mouth Oral Rinse helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

G•U•M® HYDRAL™ Dry Mouth Oral Spray helps soothe oral tissue and relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness

Indications for Use Discussion

The intended use statements of the G•U•M® HYDRAL™ Dry Mouth Oral Gel, G•U•M® HYDRAL™ Dry Mouth Oral Rinse and G•U•M® HYDRAL™ Dry Mouth Oral Spray are the same as the predicate devices; hence there are no differences in the intended therapeutic use of the device, both the subject and predicate devices are intended to relieve and manage symptoms of dry mouth.

Technological Characteristics

G•U•M® HYDRAL™ Dry Mouth Oral Gel, G•U•M® HYDRAL™ Dry Mouth Oral Rinse and G•U•M® HYDRAL™ Dry Mouth Oral Spray are intended for over the counter use and are provided ready to use. The predicate and the proposed devices use the same fundamental technology. The mode of action of G•U•M® HYDRAL™ Dry Mouth Oral Gel, G•U•M® HYDRAL™ Dry Mouth Oral Rinse and G•U•M® HYDRAL™ Dry Mouth Oral Spray are substantially equivalent to that of the predicate devices (Biotene® Oral Balance® Dry Mouth Moisturizing Gel and Biotene Dry Mouth Oral Rinse and Biotene Dry Mouth Spray, K123731).

Both the proposed and predicate devices contain ingredients such as water, humectants/moisturizers, sweeteners, flavors and preservatives. The proposed and predicate devices are also similar in design and packaging. Below is a summary of the technological characteristics compared to the primary predicate device:

Table 1: Comparison of Technological Characteristics

Parameter	**G•U•M® HYDRAL™**	**Biotene® K123731**
Gel		
Appearance	Clear, translucent gel	clear, transparent gel
Color	Colorless to Pale Yellow	clear, colorless
Odor	slight mint odor	odorless
pH	5.5 to 7.0	5.5 to 7.0
Viscosity	120,000 cps	146,600 cps
Specific Gravity	1.11	1.18
Rinse		
Appearance	clear, transparent liquid	clear, transparent liquid
Color	clear, colorless	clear, colorless
Odor	slight mint odor	spearmint odor
pH	5.5 to 7.0	5.5 to 7.0
Viscosity	20.39 Sct	10.26 Sct
Specific Gravity	1.06	1.08
Spray		
Appearance	clear, transparent liquid	clear, transparent liquid
Color	clear, colorless	clear, colorless
Odor	slight mint odor	spearmint odor
pH	5.5 to 7.0	5.5 to 7.0
Specific Gravity	1.06	1.10

Discussion of differences

The formulations for the submission devices differ from those of the predicate device; however, many of the submission device components have been cleared for use in previously FDA cleared devices with the same or highly similar indications for use.

The variations in the formula / composition do not affect the function, indications or equivalency of the proposed products, they are primarily related to viscosity control and flavor. In summary, these differences in formulation to the predicate devices do not alter the function, indications, or substantial equivalency of the products. Any new components/ingredients are designated as GRAS ingredients, food additives or have a significant history of use in dental and medical or food applications. All components of the product have been manufactured and tested using standardized and industry accepted state of the art production/test methods. The finished products have been tested using standardized and industry accepted test methods. Additionally, we commissioned a Biological Risk Assessment of the ingredients performed by NAMSA and the results do not raise any safety questions. The report begins on page 431 and ends on page 464.

Performance Data

The following nonclinical data are included in the submission in support of substantial equivalence determination:

- Bench testing comparing predicate and proposed devices' technological characteristics was performed. It was demonstrated that predicate and proposed devices are not significantly different from each other in terms of technological characteristics.
- Shelf life Stability Report
- Biocompatibility testing in conformance with 10993-1.

Conclusion

Based upon the similarity of the intended use and fundamental technology, together with non-performance testing, GUM Hydral is substantially equivalent to K123731.